

PIP for Clement Woghiren  
Follow Up Meeting #1  
April 29, 2004

DM  
4/29/04

Objective 1: Meet with Dawn Block to discuss and agree on the necessary revisions for AQ401. Document the outcome of the meeting and draft a plan (scope of changes and timeline) to achieve the objectives.

I informed Clem that his written response was partially adequate as he did document that he met with Dawn and he documented the areas of disagreement between himself and Dawn. However, no progress was made towards resolution of the disagreements.

Objective 2: Complete a detailed plan and "needs assessment" (re: AQ401) for the transfer of the two test methods from BA to QC DP/DS laboratories. This "needs assessment" is to be completed by the due date. Sign-off by QA is not required within this timeframe.

I asked Clem about progress on this objective (due on May 6, 2004). Clem informed me that he was working on it, but did not provide me with a draft of the document.

Objective 3: Complete a detailed draft of a scientifically sound and grammatically correct tech transfer protocol for each of the two assays that need to be transferred from Development to QC.

Clem told me he was working on this (due May 13, 2004) but did not provide me with a draft of the document.

Objective 4: Take the initiative to get on the Refacto ATF team meeting agenda and provide biweekly updates to the team regarding the status of the "Needs Assessment" documents and the tech transfer protocol documents.

This was not discussed at the meeting, however the next Refacto ATF meeting is scheduled for May 4, 2004. A request for agenda items was sent out today.

Objective 5: Record daily job-related activities in a logbook so that your daily work activities may be accurately quantified. The log should include specific tasks, time utilized on each task and the date of the activity. The log will be reviewed during our weekly one-on-one meetings.

Clem did not meet this objective. He did not record his activities.

WYETH00339

Minutes of meeting (27 April 2004) with Dawn Block regarding AQ401 interpretations

- I opened by stating that when AQ401 became effective, we were interested in obtaining some experience with this new SOP and after a certain period obtain best practice.
- I asked if she had any specific change in mind for this SOP. She mentioned that she was considering stating in the SOP to mandate conclusion of the needs assessment before onset of transfer activities. I offered that while this may be the ideal situation we should strive for, but we may not always have the luxury of time to conclude such a document with QRM documentation and reviews, and obtaining all approvals including QA before initiating transfer. Actual practice have shown that a needs assessment can take from a few to several weeks to complete depending on the complexity of the method and the source. Their microbiology methods are usually more straightforward. She wanted to ensure that analysts somehow document their needs assessment before onset of activities. I offered that this is actual practice and that lab management is able to have the pertinent information prior to onset of transfer activities. I suggested incorporation a form with a checklist of essential activities that would need to be checked off before transfer activities.
- Dawn believes that a method transfer and method validation has to be linked. In other words, the transfer is not complete until the method is validated. I explained that they are two distinct activities however related. There are situations where methods are transferred before a validation is done. The method could go through a revision and the validation could employ different conditions that were in the original method.
- Also, Dawn is equating the needs assessment SOP which was developed much earlier to a recent QSE requirement for the TTOC (or TT team) to have a tech transfer plan. Additionally, she believes that the needs assessment (therefore the tech transfer plan) should be written by a team, not an individual as is currently done.
- I have requested a follow up meeting and has been scheduled for 30 Apr 04

PIP for Clement Woghiren  
Follow Up Meeting #2  
May 6, 2004

DM  
7 May 04

Objective 1: Meet with Dawn Block to discuss and agree on the necessary revisions for AQ401. Document the outcome of the meeting and draft a plan (scope of changes and timeline) to achieve the objectives.

I informed Clem that his written response was partially adequate as he did document that he met with Dawn again. However, the summary that Clem provided did not address the issues that were originally discussed with Clem as being problematic. Clem did not identify the changes or the timeline as specified in the PIP. In addition, Clem did not take the initiative to make the changes. Clem documented that the revisions would be made by Dawn and that she would provide them to him for concurrence. I

Objective 2: Complete a detailed plan and "needs assessment" (re: AQ401) for the transfer of the two test methods from BA to QC DP/DS laboratories. This "needs assessment" is to be completed by the due date. Sign-off by QA is not required within this timeframe.

Clem met this objective in that he did provide me with a draft of the "needs assessment" for my review.

Objective 3: Complete a detailed draft of a scientifically sound and grammatically correct tech transfer protocol for each of the two assays that need to be transferred from Development to QC.

Clem told me he was working on this (due May 13, 2004) but did not provide me with a draft of the document.

Objective 4: Take the initiative to get on the Refacto ATF team meeting agenda and provide biweekly updates to the team regarding the status of the "Needs Assessment" documents and the tech transfer protocol documents.

Clem did not meet this objective. A Refacto ATF team meeting was held on May 4<sup>th</sup>, 2004. Clem did not provide an update to the team nor did he attend the meeting.

Objective 5: Record daily job-related activities in a logbook so that your daily work activities may be accurately quantified. The log should include specific tasks, time utilized on each task and the date of the activity. The log will be reviewed during our weekly one-on-one meetings.

Clem did not meet this objective. He did not record his activities.

WYETH00341

PIP for Clement Woghiren  
Follow Up Meeting #3 DM  
May 13, 2004

Objective 1: Meet with Dawn Block to discuss and agree on the necessary revisions for AQ401. Document the outcome of the meeting and draft a plan (scope of changes and timeline) to achieve the objectives.

Clem was able to summarize two changes that Dawn was making to AQ401. However, I informed Clem that he needed to take more initiative in getting this document revised as he told me Dawn would not be revising it until June. Clem agreed to talk to Dawn with the suggestion of the revisions being initiated by Clem.

Objective 2: Complete a detailed plan and "needs assessment" (re: AQ401) for the transfer of the two test methods from BA to QC DP/DS laboratories. This "needs assessment" is to be completed by the due date. Sign-off by QA is not required within this timeframe.

Clem met this objective in that he did provide me with a draft of the "needs assessment" for my review last week. I reviewed the document and gave Clem feedback today. In general, the feedback I provided to Clem was based around the quality and completeness of the written document (about 4 pages of text). The "purpose" section of the document written by Clem listed only one of the two methods that were covered by the text of the document, the governing SOP was not mentioned or referenced and there were a number of grammatical/spelling errors and content inconsistencies throughout the text.

Objective 3: Complete a detailed draft of a scientifically sound and grammatically correct tech transfer protocol for each of the two assays that need to be transferred from Development to QC.

Clem met this objective in that he provided me with drafts of the two documents. I told Clem I would review the documents and provide him with feedback at our next scheduled meeting.

Objective 4: Take the initiative to get on the Refacto ATF team meeting agenda and provide biweekly updates to the team regarding the status of the "Needs Assessment" documents and the tech transfer protocol documents.

There was no action on this objective, as the Refacto team meeting will not meet again until May 18<sup>th</sup>. This has been an outstanding objective for Clem (since January 2004). Clem has updated the Refacto ATF team once, on Jan. 27, 2004. The Refacto ATF team typically meets every other week.

WYETH00342

Objective 5: Record daily job-related activities in a logbook so that your daily work activities may be accurately quantified. The log should include specific tasks, time utilized on each task and the date of the activity. The log will be reviewed during our weekly one-on-one meetings.

Clem did not meet this objective. He did not record his activities. I again explained the need for the completion of this objective but Clem refused to record his activities.

Objective 6 (new objective): Clem was given the task of writing a Needs Assessment for transfer of the ProFIX ELISA from Development to QC. Clem requested a 2-week timeframe to be able to estimate a date of completion for the Needs Assessment. Although I told Clem that 2 weeks was excessive for evaluation of the timeframe, Clem insisted that 2 weeks was necessary. I agreed to allow Clem the 2 weeks for this task.

PIP for Clement Woghiren  
Follow Up Meeting #4  
May 20, 2004

DM

Objective 1: Meet with Dawn Block to propose that Clem would initiate the revisions for AQ401. Clem was also to delete the phrase "QC to QC" within the AQ401 document.

Clem did not meet this objective. He did not talk to Dawn and claimed to have not understood the objective.

Objective 2 (revised): Edit the "needs assessment" document (re: AQ401) for the transfer of the two test methods from BA to QC DP/DS laboratories.

Clem met this objective in that he told me the edits were already in QRM. However, Clem did not retain a copy of the document so this was not confirmed.

Objective 3: Complete a detailed draft of a scientifically sound and grammatically correct tech transfer protocol for each of the two assays that need to be transferred from Development to QC.

I reviewed the two protocols provided to me by Clem at the 5/13 meeting. Clem did not meet the objective of this assignment. The documents were grammatically incorrect, scientifically invalid (in a number of areas), lacked strategy and cited references incorrectly. Clem stated he had new versions of these documents on his computer with many of the corrections already incorporated. I asked Clem to provide me with a copy of these documents immediately following our meeting. Clem did not meet this objective in that he did not provide copies of these documents to me until 5/27.

Objective 4: Take the initiative to get on the Refacto ATF team meeting agenda and provide biweekly updates to the team regarding the status of the "Needs Assessment" documents and the tech transfer protocol documents.

Clem did not meet this objective.

Objective 5: Record daily job-related activities in a logbook so that your daily work activities may be accurately quantified. The log should include specific tasks, time utilized on each task and the date of the activity. The log will be reviewed during our weekly one-on-one meetings.

Clem did not meet this objective. He did not record his activities

WYETH00344

Objective 6 (new objective): Clem was given the task of writing a Needs Assessment for transfer of the ProFIX ELISA from Development to QC. Clem requested a 2-week timeframe to be able to estimate a date of completion for the Needs Assessment. Although I told Clem that 2 weeks was excessive for evaluation of the timeframe, Clem insisted that 2 weeks was necessary. I agreed to allow Clem the 2 weeks for this task.

Clem partially met the first part of the objective in that he estimated it would take 3 weeks to provide a good draft of this document. This estimate was made after 1 week as opposed to the 2-week timeframe Clem originally stated he required for the assessment.

**Christopher Pajak - today's meeting**

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**From:** Denny Maratea  
**To:** Woghiren, Clement  
**Date:** 6/2/2004 9:54 AM  
**Subject:** today's meeting  
**CC:** Pajak, Christopher

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Hi Clem,

Let's plan on meeting today at our regularly scheduled time, i.e., 1:00. As I mentioned prior to my trip to Montreal, we will discuss the progress you've made on the assignments over the last week or so, as well as the status of your performance plan. I've asked Chris Pajak to attend as I think it's important to have HR representation at these meetings. See you at 1:00.

Denny

WYETH00346



PIP for Clement Woghiren  
Follow Up Meeting #5  
June 2, 2004

DM  
3 June 2004

Objective 1: Meet with Dawn Block to propose that Clem would initiate the revisions for AQ401. Clem was also to delete the phrase "QC to QC" within the AQ401 document.

Clem partially met this objective in that he initiated a document change request form for AQ401. However, actual redlining of the document was minimal. Clem noted he just started.

Objective 2 (revised): Edit the "needs assessment" document (re: AQ401) for the transfer of the two test methods from BA to QC DP/DS laboratories.

Evaluation of edits to this document could not be made. Clem stated that the document was returned from QRM and reviewed by Bob Kitchen. The document was then passed on to John Sullivan for review. Clem did not retain a copy of the edited document and agreed to follow up with John regarding return of the document.

Objective 3: Complete a detailed draft of a scientifically sound and grammatically correct tech transfer protocol for each of the two assays that need to be transferred from Development to QC.

Clem did not meet this objective. Clem faxed me revised versions of the two documents that I had previously reviewed and returned to him with suggestions, edits, requests for clarification and additional detail. These new versions were scientifically invalid (in a number of areas), transfer strategies were unclear and inconsistent with current practices and acceptance criteria were poorly defined.

Objective 4: Take the initiative to get on the Refacto ATF team meeting agenda and provide biweekly updates to the team regarding the status of the "Needs Assessment" documents and the tech transfer protocol documents.

Clem met this objective.

Objective 5: Record daily job-related activities in a logbook so that your daily work activities may be accurately quantified. The log should include specific tasks, time utilized on each task and the date of the activity. The log will be reviewed during our weekly one-on-one meetings.

Clem did not meet this objective. He did not record his activities.

WYETH00347

Objective 6 (new objective): Clem was given the task of a Needs Assessment for transfer of the ProFIX ELISA from Development to QC. Clem estimated it would take 3 weeks to provide a good draft of this document. However, no start date was discussed.

There was no action on this agenda item as there was no timeframe discussed at our previous meeting.

Objective 7 (new objective):

Provide estimated timelines for the following projects by the end of the day on 6/3/04.

- answer trainer questions pertaining to revisions of SOP AQ401.
- design a form to replace the Needs Assessment report
- completion of draft of Needs Assessment for FIX ELISA transfer
- review validation report for A<sub>280</sub> assay for Refacto AF
- revise the two tech transfer documents for Refacto AF

Objective 8 (new objective):

Follow up with signatories of AD180 (Technology Transfer Oversight at Wyeth BioPharma, Andover) as I have concerns that we may not be following the SOP in terms of the transfer of the two Refacto assays and the FIX ELISA. I requested signatory information from QRM and will provide Clem with the information as soon as it is available to me.

Objective 9 (new objective):

Follow up with appropriate personnel (I suggested David Holmes and/or Lindsey Roberts) regarding the practice of transferring non-validated/non-qualified assays into QC.

I also notified Clem that we were extending the PIP until June 17<sup>th</sup>, 2004.

WYETH00348

Give Timeline to Dums

- ① Revision to AD 401 (to include proposed table and edits from me only) 6/18
- ② Answer Trans & 6/7
- ③ Review Val. Report for UV 6/11
- ④ Make edit to Tech Trans Protocols 6/11
- ⑤ To follow up w/ the signers of AD 180
- ⑥ 1st Draft Pro Fix Needs Assessment 6/25

SIGNATURE \_\_\_\_\_

READ AND UNDERSTOOD \_\_\_\_\_

DATE \_\_\_\_\_ 20 \_\_\_\_\_

DATE \_\_\_\_\_ 20 \_\_\_\_\_

WYETH00349

Received from Clem  
6/3/04 2:00 pm.  
DM

PIP for Clement Woghiren  
Follow Up Meeting #8  
July 1, 2004

DM  
7/2/04

Objective 1 (revised):

Clem agreed to evaluate (by 6/18) the list of SOPs in AQ401 for relevancy and to delete those that are either irrelevant or obsolete.

Clem partially met this objective. He deleted documents that are obsolete, revised document titles where necessary but did not add new documents to the list. Two of these documents were recently discussed in our meetings (2 weeks ago). They are AD180, "Technology Transfer Oversight at Wyeth BioPharma, Andover" and FD147, "Numbering and Format of analytical Method Transfer Qualification Protocols and Analytical Method Transfer Qualification Reports".

Objective 2 (revised):

Clem agreed to discuss his strategy (by 6/18) for replacing the Tech Transfer Plan (as specified in AD180) with the Needs Assessment form with other relevant stakeholders. Clem agreed to get buy in from other QC members of the QSE27 team. I suggested he speak to either Lyn Watson or John Lucas for a list of team members. Once buy-in is obtained, Clem will submit the form to QRM to go "into green".

Clem made progress toward meeting this objective in that he obtained the list of members from John Lucas and set up a meeting for 7/2/04.

Objective 3 (revised): Follow up with John Sullivan so that Clem can retrieve the document from John (after John's review) and edit the document (re: AQ401) for the transfer of the two test methods from BA to QC DP/DS laboratories.

Clem partially met this objective in that he obtained John's comments. However, Clem did not yet make any edits to the document based on my previous comments and John's comments. John suggested (as I had been saying) that the transfer strategy should be a co-validation. Clem agreed to edit the document to reflect the strategy.

Objective 3: Revise the two tech transfer draft documents that I reviewed and coached Clem on last week (6/17/04). These included, primarily, justification of technical transfer strategy and explanation of acceptance criteria (Clem had agreed to clarify it by incorporating a table into the document but he did not do this). Clem agreed to make these edits.

Clem did not meet this objective.

WYETH00350

Objective 4: Record daily job-related activities in a logbook so that your daily work activities might be accurately quantified. The log should include specific tasks, time utilized on each task and the date of the activity. The log will be reviewed during our weekly one-on-one meetings.

Clem did not meet this objective. He did not record his activities.

Objective 5: Clem is to provide a good draft of the Needs Assessment for transfer of the ProFIX ELISA to QC, by 7/2/04.

Clem met this objective in that he drafted the Needs Assessment for the transfer of this assay. Clem provided me with a copy for my review. I told Clem I would also ask Peri to review this document.

PIP for Clement Woghiren  
Follow Up Meeting #9  
July 7, 2004

DM  
7 Jul 04

Objective 1 (revised):

At our last meeting on 7/1/04 Clem agreed to add recently approved documents to the document list in AQ401. They include AD180, "Technology Transfer Oversight at Wyeth BioPharma, Andover" and FD147, "Numbering and Format of analytical Method Transfer Qualification Protocols and Analytical Method Transfer Qualification Reports".

Clem did not yet meet this objective.

Objective 2 (revised):

Clem agreed to discuss his strategy for replacing the Tech Transfer Plan (as specified in AD180) with the Needs Assessment form with other relevant stakeholders. Clem had a meeting planned for 7/2/04.

Clem made progress toward meeting this objective in that he met with John Lucas, Lyn Watson, Gabe Escobar, Dawn Block and Lindsey Roberts. Based on Clem's description of the meeting, he got a lot of "push back" from the other stakeholders. Meeting minutes are not available and the only two action items from Clem's meeting are that the attendees would each review Clem's proposed form for their needs and Clem would speak to Bev Potter regarding his proposal. There were no time frames associated with these two action items.

Objective 3 (revised):

Rewrite the Needs Assessment document and/or tech transfer documents (for Refacto) to reflect the strategy (as suggested by myself and John Sullivan) to transfer the method to QC as a co-validation between QC and BA.

Clem did not meet this objective.

Objective 4 (revised):

Revise the two tech transfer draft documents to include, justification of technical transfer strategy and explanation of acceptance criteria (Clem had agreed to clarify it by incorporating a table into the document).

Clem did not meet this objective.

WYETH00352

Objective 5 (revised):

Record daily job-related activities in a logbook so that your daily work activities might be accurately quantified. The log should include specific tasks, time utilized on each task and the date of the activity. The log will be reviewed during our weekly one-on-one meetings.

Clem did not meet this objective. He did not record his activities.

Objective 6 (revised):

Clem is to provide a good draft of the Needs Assessment for transfer of the ProFIX ELISA to QC, by 7/2/04.

Clem met this objective in that he drafted the Needs Assessment for the transfer of this assay. Clem provided me with a copy for my review on 7/1/04. Peri and I reviewed the document and gave Clem feed back today. My overall concern and comment to Clem on this document was that I was disappointed in the quality of the work. Clem cut and pasted from the original version of the Refacto assay Needs Assessment and did not include the many extensive edits that we discussed on the previous document. The same grammatical errors, format errors and insufficient text were included in the new document. Peri expressed similar concerns and in some cases her criticisms were more extensive and detailed.

As a result of the poor quality of work, I told Clem I was uncomfortable extending the PIP a second time and I was putting him on 30-day notice, until August 6, 2004. I told Clem it was his responsibility to turn this around. I also told Clem that I knew he was intelligent, had a good educational background and extensive experience and I had no doubt that he could do this work. I told Clem I didn't understand why he wasn't doing it. I told him we would meet weekly to follow up on progress as we had been. Chris Pajak told Clem that this was in no way over and that he had seen (a number of times) things turn around for employees.

Peri, Chris and I signed the "On Notice" document. Clem opted not to sign it at this point. Chris noted this on the form. I provided Clem with a copy of the "On Notice" document for his review. The meeting ended.

**Christopher Pajak - follow up**

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**From:** Denny Maratea  
**To:** Woghiren, Clement  
**Date:** 8/24/2004 9:18 AM  
**Subject:** follow up  
**CC:** Ozker, Peri; Pajak, Christopher

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Clem,

I'll be setting up an appointment for later this week or early next week so that we can discuss the status of the tech transfer projects/documents.

Also, as a result of your time away from work, we will re-initiate your entry into the "On Notice Program", effective today, Tues, August 24th. As stated previously, one's entry into the "On Notice Program" may last up to 30 days. In this case that date is September 24th.

Denny

WYETH00354



On Notice Program for Clement Woghiren  
 Follow Up Meeting #1  
 August 30, 2004

on 2 Sept. 04  
 for 14 Sept 04

AP  
 15 Sept 04

### General Summary of Meeting

Clem made insignificant progress towards his previously stated objectives (outlined below). Clem stated that he spent his time back "catching up on projects" and "in training". His reported activities were that he met with Gabe Escobar and tried to set up a meeting with Bev Potter. Clem did not take the initiative to tell us what he had been working on. Although prompted a number of times, Clem was not able to articulate the status/progress of the projects that he had been working on prior to his leave of absence from work. Peri made a number of suggestions so that Clem could clearly articulate his proposals to the stakeholders. Her suggestions included redlining a document so that one could understand his proposals. Peri also requested that AQ401 clarify the requirements for team members, their responsibilities and targets for milestones/project completion.

### Objective 1 (revised):

At our last meeting, on 7/7/04, Clem agreed to add recently approved documents to the document list in AQ401. They include AD180, "Technology Transfer Oversight at Wyeth BioPharma, Andover" and FD147, "Numbering and Format of analytical Method Transfer Qualification Protocols and Analytical Method Transfer Qualification Reports".

Clem did not yet meet this objective nor was there any progress towards meeting this objective.

### Objective 2 (revised):

It was previously noted that Clem had a meeting to discuss his strategy for replacing the Tech Transfer Plan (as specified in AD180) with the Needs Assessment form with other relevant stakeholders 7/2/04.

Meeting minutes from Clem's meeting on 7/2/04 are still not available and there was no progress on the only two action items that came out of that meeting. Clem did not yet follow up with the attendees to get their feedback on the proposed form and Clem did not yet schedule a meeting with Bev Potter.

WYETH00355

Objective 3 (revised):

Rewrite the Needs Assessment document and/or tech transfer documents (for Refacto) to reflect the strategy (as suggested by myself and John Sullivan) to transfer the method to QC as a co-validation between QC and BA.

Clem stated that this was no longer necessary since it turned out that both methods had in fact been validated previously. I asked Clem for clarification as he documented in his Needs Assessment that a revalidation was required. Clem did not provide a response to this request for clarification.

Objective 4 (revised):

Revise the two tech transfer draft documents to include, justification of technical transfer strategy and explanation of acceptance criteria (Clem had agreed to clarify it by incorporating a table into the document).

Clem did not meet this objective nor was there any progress towards meeting this objective.

Objective 5 (revised):

Record daily job-related activities in a logbook so that your daily work activities might be accurately quantified. The log should include specific tasks, time utilized on each task and the date of the activity. The log will be reviewed during our weekly one-on-one meetings.

Clem did not meet this objective. He did not record his activities.

Objective 6 (revised):

Clem is to provide a revised draft of the Needs Assessment for transfer of the ProFIX ELISA to QC. A number of edits and suggestions for clarification and grammatical corrections were provided to Clem on our previous meeting of 7/7/04.

Clem did not make any progress towards editing this document.

### Summary of Expectations

We told Clem that we would set up a meeting for next week to follow up on a number of items. These items included the six documents that required various revisions and/or rewrites. They are:

**AQ283** (Clem has proposed changes for clarity)

**AQ401** ("in green" and comments previously provided to Clem)

**Needs Assessment for two Refacto assays** ("in green" and comments previously provided to Clem)

**Tech Transfer Qualification Protocol for Refacto assay UV-VIS for protein content** (comments previously provided to Clem)

**Tech Transfer Qualification Protocol for Refacto assay rpHPLC** (comments previously provided to Clem)

**Needs Assessment document for ProFIX ELISA** (comments previously provided to Clem)

It was pointed out that a number of these documents could be edited to address comments provided (in writing) to Clem at our last meeting (prior to his leave of absence).

On Notice Program for Clement Woghiren

Follow Up Meeting #2

September 7, 2004

PM 15 Sept 04  
PR 16 Sept 04  
CR 16 Sept 04

### General Summary of Meeting

Clem made little progress towards his previously stated objectives (outlined below). His reported activities were that he redlined the scope section of AQ401 (but did not incorporate the other changes that were previously provided to Clem by Peri and/or Denny) including the request to clarify the requirements for team members, their responsibilities and targets for milestones/project completion. Clem also reported that he met with Bev Potter and she agreed to add the definition of the TTOC (defined in AD180) to AQ283. Clem made this change but needs to meet with other stakeholders prior to submitting it to QRM.

### Objective 1 (revised):

At our last meeting, on 8/30/04, Clem agreed to add recently approved documents to the document list in AQ401. They include AD180, "Technology Transfer Oversight at Wyeth BioPharma, Andover" and FD147, "Numbering and Format of analytical Method Transfer Qualification Protocols and Analytical Method Transfer Qualification Reports".

Clem did not yet meet the objective nor was there any progress towards meeting the objective. Although Clem provided us with redlined copies of AQ401, the revisions were limited to a minor change in the wording of the scope of the document.

### Objective 2 (revised):

It was previously noted that Clem had a meeting to discuss his strategy for replacing the Tech Transfer Plan (as specified in AD180) with the Needs Assessment form with other relevant stakeholders 7/2/04.

Clem met the objective of meeting with Bev Potter and obtained agreement from her on the concept of using a form. However, meeting minutes from Clem's meeting on 7/2/04 are still not available and there was no progress one of the two action items that came out of that meeting, i.e., Clem did not yet follow up with the attendees to get their feedback on the proposed form.

WYETH00358

Objective 3 (revised):

Rewrite the Needs Assessment document and/or tech transfer documents (for Refacto) to incorporate the edits from Denny, Peri, and Sue Monahan.

Clem partially met this objective in that he provided us with a redlined copy of the document that addresses a number of comments provided to him by Peri. Clem did not address comments previously supplied to him by Denny or Sue Monahan.

Objective 4 (revised):

Revise the two tech transfer draft documents to include justification of technical transfer strategy and explanation of acceptance criteria (Clem had agreed to clarify it by incorporating a table into the document).

Clem did not meet this objective nor was there any progress towards meeting this objective.

Objective 5 (revised):

Record daily job-related activities in a logbook so that your daily work activities might be accurately quantified. The log should include specific tasks, time utilized on each task and the date of the activity. The log will be reviewed during our weekly one-on-one meetings.

Clem did not meet this objective. He did not record his activities.

Objective 6 (revised):

Clem is to provide a revised draft of the Needs Assessment for transfer of the ProFIX ELISA to QC. A number of edits and suggestions for clarification and grammatical corrections were provided to Clem on our previous meeting of 8/30/04.

Clem did not make any progress towards editing this document.

WYETH00359

### Summary of Expectations

Denny told Clem that his productivity over the last week is not meeting expectations for someone at his grade level and years of experience. Expectations for the coming week were stated and are as follows:

The product specific documents are to be edited to address all comments previously provided to Clem. These documents include:

**Tech Transfer Qualification Protocol for Refacto assay UV-VIS for protein content** (comments previously provided to Clem)

**Tech Transfer Qualification Protocol for Refacto assay rpHPLC** (comments previously provided to Clem)

**Needs Assessment document for ProFIX ELISA** (comments previously provided to Clem)

Clem needs to resolve the key issue of the timing requirement for completion of the Needs Assessment with respect to other technical transfer activities.

Clem needs to meet with Sue Monahan, Gabe Escobar, Dawn Block, John Lucas and Lynn Watson for consensus on document revisions.

In addition, the minor revision to AQ283 (addition of a definition) should be submitted to QRM.

Clem was also asked for a brief summary plan on his strategy/thought-process for completing the assigned objectives.

Both Peri and Denny will review the edits Clem made to AQ401 and the Needs Assessment for the two Refacto assays. We will provide feedback to Clem at our next meeting to be scheduled the week of Sept. 13<sup>th</sup>.

WYETH00360

On Notice Program for Clement Woghiren  
Follow Up Meeting #3  
September 15, 2004

DM 17 Sept 04  
PR 17 Sept 04  
Q 20 Sep 04

General Summary of Meeting

In general, Clem was inarticulate regarding the tech transfer project and the process by which the various documents link together. Clem made some progress towards his previously stated specific objectives (outlined below). His reported activities were that he updated the two Refacto AF specific tech transfer protocols with comments provided to him previously and he made some minor changes to AQ401. Clem provided copies of the following documents to Denny and Peri for review:

Needs Assessment for the two Refacto AF specific assays (a single document)

AQ283 (with revisions)

AQ401 (with revisions)

Tech Transfer protocol for the rpHPLC method for Refacto AF

Tech Transfer protocol for the UV method for Refacto AF

Clem also met with Dawn Block and John Lucas.

Objective 1 (revised):

The product specific documents are to be edited to address all comments previously provided to Clem. These documents include:

**Tech Transfer Qualification Protocol for Refacto assay UV-VIS for protein content** (comments previously provided to Clem)

**Tech Transfer Qualification Protocol for Refacto assay rpHPLC** (comments previously provided to Clem)

Clem states that he met this objective in that he made the edits and submitted the documents to QRM. Clem provided (at Denny's request) a copy of the documents that were submitted to QRM. Denny and/or Peri will review these documents for content and clarity.

Objective 2 (revised):

Clem needs to resolve the key issue of the timing requirement for completion of the Needs Assessment with respect to other technical transfer activities.

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Clem did not meet this objective. There was no text written into AQ401 to address this concern.

Objective 3 (revised):

Clem needs to meet with Sue Monahan, Gabe Escobar, Dawn Block, John Lucas and Lynn Watson for consensus on document revisions.

Clem partially met this objective in that he met with Dawn and John. However, Clem attempted to get buy-in from each of the two mentioned stakeholders but did not provide them with a copy of the associated SOP, i.e., AQ401.

Objective 4 (revised):

The minor revision to AQ283 (addition of a definition) should be submitted to QRM once the stakeholders agree to the change.

Clem did not meet this objective.

Objective 5 (revised):

Clem was to provide a brief summary plan on his strategy/thought-process for completing the assigned objectives.

Clem did not meet this objective.

Objective 6 (revised):

Record daily job-related activities in a logbook so that his daily work activities might be accurately quantified. The log should include specific tasks, time utilized on each task and the date of the activity. The log will be reviewed during weekly follow up meetings.

Clem did not meet this objective. He did not record his activities.

Objective 7 (revised):

Clem is to provide a revised draft of the Needs Assessment for transfer of the ProFIX ELISA to QC. A number of edits and suggestions for clarification and grammatical corrections were provided to Clem at a previous meeting (8/30/04).

Clem did not make any progress towards editing this document. However, this was not assigned to Clem as one of the priority tasks.

WYETH00362



Summary of Meeting

Both Denny and Peri expressed concern that the flow of the documents and the transfer system was unclear and lacked the necessary detail. When asked for specifics, Clem was unable to give a clear and consistent response. At one point he stated that the transfer form he developed was only for one or two assays. Since this was the first time this was mentioned and it's not stated in the documents, Denny asked for additional clarification and an explanation regarding the mechanism of transferring a larger number of assays as part of a single project. Clem responded that then there would need to be a plan. This comment is inconsistent with his previous comments that the form could also serve as the plan. Denny told Clem that she was concerned that every time we spoke about the project a new intent, concept and/or objective was stated.

Denny expressed concern that Clem wasn't thinking strategically and that the documents were in a continual state of revision with no targeted endpoint/date. Denny told Clem that at his level of experience, it was expected that Clem would think strategically about the system prior to putting it in words.

In addition, it appeared that there is minimal or an unsuccessful attempt on Clem's part to make the documents consistent with each other. Both Peri and Denny requested (as in the previous week) that Clem prepare a brief project plan (half page) outlining the deliverables and the targeted dates. Clem agreed. It was also requested that Clem fill in the draft form with information as a means of checking the adequacy of the form. Peri had suggested the example use of the form at the two prior meetings as a way of proofing the concepts and as a means of facilitating meetings with stakeholders. Clem initially objected, as he did in the previous meetings, and said it would take a long time to do that. However, by the end of the meeting he agreed to do a test run of the form.

Denny asked Clem as to his vision of how much he could accomplish by the next meeting (to be scheduled in about 1 week). Clem replied that he could revise the form and fill it in. Denny challenged Clem as 40 hours seemed excessive for this task.

Expectations for Week's Work

Complete the form for the Needs Assessment

Fill in a form as an example, i.e., test run of the form

Outline how the various documents fit together, i.e., outline the process for tech transfer in general terms

Summarize the documents that are to be completed and indicate the steps for completing the revisions.

On Notice Program for Clement Woghiren

Follow Up Meeting #4 DM

September 22, 2004

per 081104 CP 10 Nov 04

General Summary of Meeting (attended by Clem Woghiren, Denny Maratea, Peri Ozker and Chris Pajak)

Denny asked Clem if he wanted to talk about his accomplishments over the previous week. Clem responded by asking Denny to refresh for him the items that he was to work on during the previous week. Denny read the list of items from her notes. They were as follows:

- Complete the form for Needs Assessment
- Fill in the form as an example, i.e., test run of the form
- Outline how the various documents fit together, i.e., outline the process for tech transfer in general terms.
- Summarize the documents that are to be completed and indicate the steps for completing the revisions.

Objective 1 (revised):

Complete the form for the Needs Assessment and provide an example as to how the form would be used for capturing the necessary information. It was agreed that the example could be a "made up" method transfer.

Clem completed the form and provided an example of a "filled out" form to demonstrate the usefulness of the form. Clem began to talk Denny and Peri through the use of the Needs Assessment form, per AQ401. After several minutes of discussion, Peri expressed concern with the lack of relevant information that could be captured on the form. For instance, there was no mechanism for recording roles and responsibilities of the team members that would be signing the form, i.e., tasks, due dates and assignees. Clem's response was that the information could be captured in meeting minutes instead of the form. Peri pointed out that the primary purpose of the form was to capture and document these items and that meeting minutes were unacceptable for this purpose. The form was also problematic in that it was not designed to document multiple assay transfers or to separate the various phases of the project. For example, significance of a signature on the form in terms of the project status was unclear. An individual might sign the form signifying that there was agreement as to what needed to be done but there was no accommodation for a signature following completion of the task.

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Objective 2 (revised):

Outline how the various documents fit together, i.e., outline the process for tech transfer in general terms.

The purpose of the request for Clem to put this flow diagram together was to assist Clem in explaining his strategic plan for this process. However, Clem provided a flowchart comprised of 3 boxes with very little information incorporated into the process. Denny and Peri agreed with the high level flow but indicated that the diagram lacked the necessary detail for clarity. Throughout the conversation, Denny asked questions but Clem's response was generally very high level. He was not able to articulate the appropriate and necessary detail. Denny also raised concerns that Clem has been changing his plan and/or the scope/purpose of AQ401 on a weekly basis. Clem was resistant to this feedback and did not agree with Denny's assessment.

Objective 3 (revised):

Clem was to summarize the documents that are to be completed and indicate the steps for completing the revisions (second request).

Clem provided a one-page written plan that summarized the documents he has been working on and a high level plan as to the process that he envisions for bringing these documents to completion. Clem provided the status of the documents and in all cases Clem suggested that if after review there were no major changes to the document text, the documents would be done in 6 weeks. Denny provided feedback to Clem that she was expecting to have more detail on how a change in one of these documents impacts the others and how the documents relate to each other from a process point of view. Denny reiterated her concern about the lack of strategic thought that was being applied to the project.

Objective 4 (revised):

On Sept. 15, 2004, Clem provided (at Denny's request) a copy of the two documents that he submitted to QRM. These documents include:

**Tech Transfer Qualification Protocol for Refacto assay UV-VIS for protein content**

**Tech Transfer Qualification Protocol for Refacto assay**

Denny and Peri reviewed these documents for content and clarity and provided feedback to Clem at the September 22<sup>nd</sup> meeting.

WYETH00365

Denny gave Clem positive feedback in that the documents were in much better shape now and only a few additional but minor comments/suggestions were provided. Clem was open to these comments. Denny then expressed concern that Clem needed another 6 weeks before these documents could go into the final approval process, especially since it had taken more than 3 months to get the documents to their current status.

Objective 5 (revised):

Record daily job-related activities in a logbook so that his daily work activities might be accurately quantified. The log should include specific tasks, time utilized on each task and the date of the activity. The log will be reviewed during weekly follow up meetings.

Clem did not meet this objective. He did not record his activities.

Objective 6 (revised):

Clem is to provide a revised draft of the Needs Assessment for transfer of the ProFIX ELISA to QC. A number of edits and suggestions for clarification and grammatical corrections were provided to Clem at a previous meeting (8/30/04).

Clem did not make any progress towards editing this document. However, this was not assigned to Clem as one of the priority tasks.

Summary of Meeting

Similar to the conclusions of the previous meeting, Denny and Peri expressed concern that Clem wasn't thinking strategically and that the documents were in a continual state of revision with no targeted endpoint/date. The flow of the documents and the assay technology transfer system was unclear and lacked the necessary detail. When asked for specifics, Clem was unable to articulate a clear and consistent response.

Denny stated that we'd follow up with Clem in a few days. She reminded Clem the "On Notice" program was to end on Sept. 24<sup>th</sup> and that she would discuss the status with her management as well as with HR. Clem followed up by summarizing what he would be working on during the next week, i.e., he would clean up the example he had provided to Peri and Denny for review and he would mention the form in the SOP AQ401.

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